UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,228	11/25/2003	Michael P. Caren	10021301-1	6698

7590 06/15/2006

AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER	
CROW, ROBERT THOMAS	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,228	CAREN ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *12-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 16 May 2006 is acknowledged. The traversal is on the ground(s) that the method claims are already dependent upon the device of claim 1. These remarks are noted but are not found persuasive because, as outlined in the Requirement for Restriction dated 1 May 2006, the inventions are distinct if the product as claimed can be used in a materially different process of using that product. As stated in the Requirement for Restriction, the device of Group I can be used as a cell culture device. Any discussion of the prior art is only appropriate upon examination of the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-25 are therefore withdrawn. Claims 1-11 are currently under prosecution.

Information Disclosure Statement

The Information Disclosure Statement filed 25 November 2003 is acknowledged. However, most of the references cited lack proper document numbers (e.g., 0,045,274 dated 10 April 2002). While the subject matter of the U.S. Patent documents is presumed to have been included in a search of EAST, the actual documents listed in the Information Disclosure Statement are not being considered as the actual identities of the documents listed therein are unknown.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1-11 are indefinite in claims 1, 4, 7, and 11, which recite the limitations "(larger chamber)" and "(smaller chamber)" in lines 2-3 of claim 1, lines 4-5 of claim 4, lines 5-6 of claim 7, and lines 5-6 of claim 11. It is unclear if the phrase within the parentheses is a limitation of the claim.

2. Claim 9 is indefinite in the recitations "CCD" in line 1 of the claim and "CMOS" in line 2 of the claim, because they are acronyms, the meanings of which may change over time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001).

Regarding claim 1, Anderson et al teach a device for conducting binding reactions, said device comprising: two chambers in fluid communication (e.g., a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers; column 22, lines 27-38), wherein one of said chambers (larger chamber) has a volume that is greater than a volume of the other chamber (smaller chamber) (e.g., the chambers have known varied volumes; column 18, lines 45-46), and an array of features comprising biopolymer probes, in each of the two chambers (e.g., the device has an analytical chamber including an oligonucleotide array[column 24, lines 5-6], and the device has an amplification reaction chamber having PCR primers disposed therein; column 10, lines 15-39).

Regarding claim 2, Anderson et al teach the device of claim 2 wherein the chambers have capillary dimensions (e.g., elongated reaction chambers of micron scale dimensions are used; column 18, lines 23-34).

Regarding claim 6, Anderson et al teach the device of claim 1 in communication with a detector (column 60, lines 21-47 and Figure 49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1, 3, 5, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001).

Regarding claim 3, Anderson et al teach the device of claim 1 for conducting binding reactions, said device comprising: two chambers in fluid communication (e.g., a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers; column 22, lines 27-38), wherein one of said chambers (larger chamber) has a volume that is greater than a volume of the other

chamber (smaller chamber) (e.g., the chambers have varied by known volumes; column 18, lines 45-46),and an array of features comprising biopolymer probes, in each of the two chambers (e.g., the device has an analytical chamber including an oligonucleotide array[column 24, lines 5-6], and the device has an amplification reaction chamber having PCR primers disposed therein; column 10, lines 15-39).

While Anderson et al do not teach instructions, the courts have found that "[n]onfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (combining printed instructions and an old product into a kit will not render the claimed invention nonobvious even if the instructions detail a new use for the product). Therefore, because the courts have stated that the inclusion of instructions with an old product is obvious, the instantly claimed instructions are obvious in view of Anderson et al.

Regarding claim 5, Anderson et al also teach an alternate interpretation of the device of claim 1, said device comprising: two chambers in fluid communication (e.g., a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers; column 22, lines 27-38), wherein one of said chambers (larger chamber) has a volume that is greater than a volume of the other chamber (smaller chamber) (e.g., the chambers have known varied volumes; column 18, lines 45-46), and an array of features comprising biopolymer probes, in each of the two chambers (e.g., the device has an amplification reaction chamber having PCR primers

disposed therein [column 10, lines 15-39], and a storage chamber containing PCR primers; column 38, lines 1-7).

While Anderson et al do not teach the specific sizes of each chambers, Anderson et al do teach that smaller chambers cool faster than larger volume counterparts with the added advantage that the ability to change temperature rapidly allows for rapid thermal cycling reactions (e.g., PCR; column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

Anderson et al also teach the storage chamber has sufficient solution for multiple fluid transfers (e.g., portions of solution are aliquotted from the storage chamber containing 10 microliters of fluid; column 67, lines 60-61). Anderson et al additionally teach that the device has a total PCR reaction volume of 2.5 microliters including the primer solutions (column 66, lines 20-25). Therefore, the smaller PCR chamber has a smaller number of biopolymer probe molecules that the larger storage chamber (i.e., there is more primer solution in the storage chamber than in the PCR chamber; hence,

the number of probe molecules [i.e., PCR primers] in the storage chamber is greater than the number of probe molecules [PCR primers] in the PRC chamber).

Regarding claim 7, Anderson et al an apparatus for conducting hybridization reactions, said apparatus comprising: a housing (e.g., a base unit for incorporating the reaction chamber containing portion; column 34, lines 28-38) having an interior with capillary dimensions (e.g., elongated reaction chambers of micron scale dimensions are used; column 18, lines 23-34) wherein said interior comprises at least two chambers in fluid communication (e.g., a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers; column 22, lines 27-38), wherein one of said chambers has at least one interior dimension that is larger (larger chamber) than at least one interior dimension of the other of said chambers (smaller chamber) (e.g., the device incorporates a plurality of chambers; [column 22, lines 27-38], and the chambers have known varied volumes; column 18, lines 45-46), said interior comprising a microarray of features comprising biopolymer probes (e.g., the device has an analytical chamber including an oligonucleotide array[column 24, lines 5-6], and the device has an amplification reaction chamber having PCR primers disposed therein; column 10, lines 15-39) and a detector in communication with said housing (column 60, lines 21-47 and Figure 49).

Anderson et al also teach the PCR chamber comprising probes having expected concentrations in a sample solution that are equal to or greater than a predetermined

value (e.g., PCR requires two primer sequences [column 9, lines 15-26], therefore the PCR chamber has probes for at least one copy of the sequence).

Anderson et al also teach the oligonucleotide array comprising probes that are directed to target molecules having expected concentration that are less than said predetermined value (i.e., the array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target [column 13, lines 55-60]; therefore the array has probes for target molecules that are not present in the sample; i.e., have a concentration of zero).

While Anderson et al do not teach the specific sizes of each chambers, Anderson et al do teach that smaller chambers cool faster than larger volume counterparts with the added advantage that the ability to change temperature rapidly allows for rapid thermal cycling reactions (e.g., PCR; column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

Since the PCR chamber comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a

predetermined value, the smaller chamber therefore comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value (e.g., PCR requires two primer sequences [column 9, lines 15-26], therefore the smaller PCR chamber has probes for at least one copy of the sequence). Similarly, since the oligonucleotide array comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value , the larger chamber comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value (i.e., the oligonucleotide array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target [column 13, lines 55-60]; therefore the oligonucleotide array chamber has probes for target molecules that are not present in the sample; i.e., have a concentration of zero).

Regarding claim 8, the apparatus of claim 7 is discussed above. Anderson et al also teach the apparatus wherein said housing is part of a microfluidic system (e.g., a base unit for incorporating the reaction chamber containing portion; column 34, lines 28-38).

Regarding claim 9, Anderson et al teach the apparatus of claim 7, wherein said detector is a CCD (column 16, lines 60-62).

Regarding claim 10, Anderson et al teach the apparatus of claim 7, further comprising a fluid dispensing device (e.g., the device applies electric currents across buffer chambers to supply electrophoresis buffers; column 24, lines 27-30).

3. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001) in view of Muller et al (U.S. Patent No. 5,804,384, issued 8 September 1998).

Regarding claim 4, Anderson et al teach the device of claim 1 for conducting binding reactions, said device comprising: two chambers in fluid communication (e.g., a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers; column 22, lines 27-38), said chambers each having an interior with capillary dimensions (e.g., elongated reaction chambers of micron scale dimensions are used; column 18, lines 23-34), wherein one of said chambers has interior dimensions that are larger (larger chamber) than the interior dimensions of the other of said chambers (smaller chamber) (e.g., the chambers have known varied volumes; column 18, lines 45-46), each of said interiors comprising an array of features comprising biopolymer probes, in each of the two chambers (e.g., the device has an analytical chamber including an oligonucleotide array[column 24, lines 5-6], and the device has an amplification reaction chamber having PCR primers disposed therein; column 10, lines 15-39).

Anderson et al also teach the PCR chamber comprising probes having expected concentrations in a sample solution that are equal to or greater than a predetermined value (e.g., PCR requires two primer sequences [column 9, lines 15-26], therefore the PCR chamber has probes for at least one copy of the sequence).

Anderson et al also teach the oligonucleotide array comprising probes that are directed to target molecules having expected concentration that are less than said predetermined value (i.e., the array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target [column 13, lines 55-60]; therefore the array has probes for target molecules that are not present in the sample; i.e., have a concentration of zero).

While Anderson et al do not teach the specific sizes of each chambers, Anderson et al do teach that smaller chambers cool faster than larger volume counterparts with the added advantage that the ability to change temperature rapidly allows for rapid thermal cycling reactions (e.g., PCR; column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

Since the PCR chamber comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value, the smaller chamber therefore comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater

than a predetermined value (e.g., PCR requires two primer sequences [column 9, lines 15-26], therefore the smaller PCR chamber has probes for at least one copy of the sequence). Similarly, since the oligonucleotide array comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value , the larger chamber comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value (i.e., the oligonucleotide array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target [column 13, lines 55-60]; therefore the oligonucleotide array chamber has probes for target molecules that are not present in the sample; i.e., have a concentration of zero). Anderson et al are silent with respect to linear arrays.

However, Muller et al teach a device having capture probes specific for a target analyte wherein the probes are arranged in linear arrays (Abstract) with the added advantage that linear arrays generate signals that resemble a barcode in the device (column 1, lines 50-52).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the arrayed devices as taught by Anderson et al with the linear arrays of Muller et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in generation of signals that resemble a barcode in the device as explicitly taught by Muller et al (column 1, lines 50-52).

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001) in view of Wu et al (U.S. Patent No. 6,221,677 B1, issued 24 April 2001).

Regarding claim 11, Anderson et al teach at least two chambers in fluid communication (e.g., a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers; column 22, lines 27-38), said chambers each having an interior with capillary dimensions (e.g., elongated reaction chambers of micron scale dimensions are used; column 18, lines 23-34), wherein one of said chambers has interior dimensions that are larger (larger chamber) than the interior dimensions of the other of said chambers (smaller chamber) (e.g., the chambers have known varied volumes; column 18, lines 45-46), each of said interiors comprising an array of features comprising biopolymer probes, in each of the two chambers (e.g., the device has an analytical chamber including an oligonucleotide array[column 24, lines 5-6], and the device has an amplification reaction chamber having PCR primers disposed therein; column 10, lines 15-39).

While Anderson et al do not teach the specific sizes of each chambers, Anderson et al do teach that smaller chambers cool faster than larger volume counterparts with the added advantage that the ability to change temperature rapidly allows for rapid thermal cycling reactions (e.g., PCR; column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

Since the PCR chamber comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value, the smaller chamber therefore comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value (e.g., PCR requires two primer sequences [column 9, lines 15-26], therefore the smaller PCR chamber has probes for at least one copy of the sequence). Similarly, since the oligonucleotide array comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value , the larger chamber comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value (i.e., the oligonucleotide array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target [column 13, lines 55-60]; therefore the oligonucleotide array chamber has probes for target molecules that are not

present in the sample; i.e., have a concentration of zero). Anderson et al are silent with respect to linear arrays.

However, Wu et al teach an elongated web comprising a linear array of biopolymer features (e.g., a channel having single reporter beads contained therein [column 8, lines 1-16], wherein the reporter beads are sensitive to analytes; column 7, lines 8-12) wherein said linear array is from 1-5 features in width (e.g., the beads are forced into a single file; column 8, lines 10-15) with the added advantage that the linear array allows the particles to be detected in a flow cytometer detection channel (column 7, line 65-column 8, line 3).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the arrayed devices as taught by Anderson et al with the linear arrays of Wu et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in allowing the particles to be detected in a flow cytometer detection channel as explicitly taught by Wu et al (column 7, line 65-column 8, line 3).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

6/12/06

BJ FORMAN, PH.D.
PRIMARY EXAMINER